

Jurisdiction Specific Medicare Part B Leukine

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Leukine	sargramostim

Covered Uses

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- Acute Myeloid Leukemia Following Induction Chemotherapy
- Autologous Peripheral Blood Progenitor Cells Mobilization and Collection
- Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation
- Allogeneic Bone Marrow Transplantation (BMT)
- Allogenic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure
- Acute Exposure to Myelosuppressive Doses of Radiation (H-ARS)
- Adjunctive treatment of neutropenia in certain conditions
- Dose dense therapy for adjuvant treatment of breast cancer
- After initial induction chemotherapy or first post-remission course of chemotherapy for acute lymphocytic leukemia
- Acute myeloid leukemia after the completion of induction or repeat induction chemotherapy
- Myelodysplastic syndrome with severe neutropenia or recurrent infection
- Exposure to radiation therapy in the absence of chemotherapy
- After a hematopoietic progenitor stem cell transplant (HPCT/HSCT)

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Administration of Leukine to increase chemotherapy dose intensity except as noted below
- Continuous use of Leukine for myelodysplastic syndrome or Felty's syndrome without infections
- Chemosensitization of myeloid leukemias
- Continued use if no response is seen within 28-42 days
- Administration in members with chronic aplastic anemia

Coverage Criteria

Induction Chemotherapy in Acute Myelogenous Leukemia

Authorization of 6 months may be granted following induction chemotherapy in members 55 years of age and older with acute myelogenous leukemia to shorten time to neutrophil recovery and reduce the incidence of severe and life-threatening infections.

Mobilization and Following Transplantation of Autologous Peripheral Blood Progenitor Cells

Authorization of 6 months may be granted for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation

Authorization of 6 months may be granted for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric members 2 years of age and older with non-Hodgkin's lymphoma, acute lymphoblastic leukemia and Hodgkin's lymphoma.

Myeloid Reconstitution after Allogenic Bone Marrow Transplantation

Authorization of 6 months may be granted for acceleration of myeloid reconstitution in members undergoing allogenic bone marrow transplantation from human leukocyte antigen (HLA)-matched related donors.

Bone Marrow Transplantation Failure or Engraftment Delay

Authorization of 6 months may be granted for members who have undergone allogenic or autologous bone marrow transplant in whom engraftment is delayed or has failed.

Other Indications

Authorization of 6 months may be granted for treatment of any of the following conditions:

- Adjunctive treatment of neutropenia when any of the conditions listed below are present:
 - Expected prolonged (greater than 10 days) and profound (less than $0.1 \times 10^9/L$) neutropenia
 - Age greater than 65 years
 - Uncontrolled primary disease
 - Pneumonia
 - Hypotension and multiorgan dysfunction (sepsis syndrome)
 - Invasive fungal infection
 - Hospitalization at the time of the development of fever
- Dose dense chemotherapy (treatment given more frequently, such as every two weeks instead of every three weeks) for adjuvant breast cancer
- After completion of the first few days of initial induction chemotherapy or for first post-remission course of chemotherapy for the treatment of acute lymphocytic leukemia (ALL)
- After the completion or repeat induction chemotherapy of AML in members over 55 years of age
- Myelodysplastic syndrome when either of the following criteria is met:
 - Absolute neutrophil count (ANC) less than or equal to $500/mm^3$
 - Member is experiencing recurrent infection
- Member receiving radiation therapy in the absence of chemotherapy if prolonged delays due to neutropenia are expected
- Accidental or intentional total body irradiation of myelosuppressive doses (greater than 2 Grays [Gy]) such as hematopoietic syndrome of acute radiation syndrome (H-ARS)
- After a hematopoietic progenitor stem cell transplant (HPCT/HSCT) for one of the following indications:
 - To promote myeloid reconstitution
 - When engraftment is delayed or has failed
 - Mobilization of progenitor cells into peripheral blood for collection by leukapheresis, as an adjunct to peripheral blood/hematopoietic stem cell transplantation (PBSCT/PHSCT)

Dosage and Administration

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason

Reference number(s)
4488-A

for additional services is not justified by documentation. Leukine will be covered when administered under direct supervision in the office setting. When administered by the member or caregiver, the drug will be considered self-administered and not payable.

References

1. White Cell Colony Stimulating Factors LCD (L37176) Version R15. Available at:
<https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.
Accessed June 19, 2024.
2. Billing and Coding: White Cell Colony Stimulating Factors (A56748) Version R12. Available at:
<https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx>.
Accessed June 19, 2024.
3. Leukine [package insert]. Lexington, MA: Partner Therapeutics, Inc.; August 2023.